# SODIUM CHLORIDE- sodium chloride irrigant Baxter Healthcare Corporation

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#### **Directions for Use of Flexible Plastic Irrigation Containers**

If desired, warm in overwrap to near body temperature in a water bath or oven heated to not more than 45°C.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

#### **DIRECTIONS FOR USE**

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired.

Use Aseptic Technique.

- 1. Suspend container using hanger hole.
- 2. Remove plastic protector from outlet port at bottom of container.
- 3. Attach irrigation set. Refer to complete directions accompanying set.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C): brief exposure up to 40°C does not adversely affect the product.

#### **Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

Printed in Mexico

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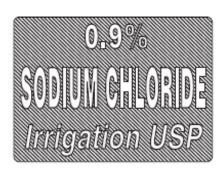
Rev. May 2017

88-80-31-833

#### PRINCIPAL DISPLAY PANEL - PACKAGING LABELING

0 ⊚ 2700 NDC 0338-0047-47

NOT FOR INJECTION



2400

2100

1800

EACH 100mL CONTAINS 900 mg SODIUM CHLORIDE USP NO ANTIMICROBIAL AGENT HAS BEENADDED pH 5.5 (4.5 to 7.0) mEq/L SODIUM 154 CHLORIDE 154 OSMOLARITY 308 mOsmol/L (calc) Sterile Nonpyrogenic SINGLE DOSE CONTAINER

1500

DO NOTUSE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION

1200

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICHMAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND RX ONLY STOREUNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

900



600

UROMATIC COINTAINER

PL 146 PLASTIC

BAXTER UROMATIC AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONALING

FOR PRODUCT INFOMATION

Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN MEXICO

300

3000 mL 2B77127 NDC 0338-0047-47

NOT FOR INJECTION

0.9% SODIUM CHLORIDE Irrigation USP

Each 100 mL contains 900 mg Sodium Chloride USP No antimicrobial agent has been added pH 5.5 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolarity 308 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container

Do not use unless solution is clear Discard unused portion

Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found **Rx Only** Store unit in moisture barrier overwrap at room temperature (25°C) until ready to use Avoid excessive heat See insert

0.9%

Sodium Chloride

NaCl

Irrigation USP

**UROMATIC** container

PL 146 plastic

BAXTER UROMATIC and PL 146 are trademarks of Baxter International Inc

For product information 1-800-933-0303

Baxter Logo Baxter Healthcare Corporation Deerfield, IL 60015 USA

Made in Mexico

2700

2400

2100

1800

1500

1200

900

600

300

2B7127

4-3000 ML VIAFLEX ® CONTAINER

0.9% SODIUM CHLORIDE IRRIGATION, USP

EXP

LOT



(01)50303380047470

4-3000 ML

VIAFLEX® CONTAINER

0.9% SODIUM CHLORIDE IRRIGATION, USP

EXP

BAR CODE

(17)180400 (10)V16028A

LOT

BAR CODE

(01) 50303380047470

### **SODIUM CHLORIDE**

sodium chloride irrigant

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0047	
Route of Administration	IRRIGATION			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	E SODIUM CHLORIDE	900 mg in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:0338-0047-44	14 in 1 CARTON	05/30/1980		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product			
2	NDC:0338-0047-46	6 in 1 CARTON	05/30/1980		
2		2000 mL in 1 BAG; Type 0: Not a Combination Product			
3	NDC:0338-0047-47	4 in 1 CARTON	05/30/1980		
3		3000 mL in 1 BAG; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA017867	05/30/1980		

## Labeler - Baxter Healthcare Corporation (005083209)

Establishment			
Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-0047), LABEL(0338-0047), MANUFACTURE(0338-0047), PACK(0338-0047), STERILIZE(0338-0047)

Establishment				
Name	Address	ID/FEI	Business Operations	
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0047)	

Establishment			
Name	Address	ID/FEI	Business Operations
Baxter, S.A. de C.V.		810432484	ANALYSIS(0338-0047), MANUFACTURE(0338-0047), LABEL(0338-0047), PACK(0338-0047), STERILIZE(0338-0047)

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